



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/712,425  | 11/13/2003  | Frank D. Lee         | ENGE-P02-001        | 9956             |
| 28120   | 7590        | 10/20/2005           | EXAMINER            |                  |
| FISH & NEAVE IP GROUP<br>ROPES & GRAY LLP<br>ONE INTERNATIONAL PLACE<br>BOSTON, MA 02110-2624 |             |                      | LIN, JERRY          |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 1631                |                  |

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/712,425

Applicant(s)

LEE ET AL.

Examiner

Jerry Lin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-125 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-125 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Notice to Comply with Sequence Rules***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§1.821 through 1.825 because it lacks any submission of a computer readable form sequence listing, a paper copy for the specification, a statement under 37 CFR §§1.821(f) and (g), and SEQ ID Nos cited along with each sequence in the specification or Figures. Applicants are also reminded that SEQ ID Nos are not required in the Figures per se, however, the corresponding SEQ ID Nos then are required in the Brief Description of the Drawings section in the specification. Applicants are also reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicant(s) are given the same response time regarding this failure to comply as that set forth to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or notice of a failure to fully respond to this Office action.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-36, drawn to a method of detecting the presence of post-translational modification, classified in class 702, subclass 19.

- II. Claims 37-43, 53, 66-74, and 84-88, drawn to an array of capture agents, classified in class 435, subclass 6.
- III. Claims 44-52, and 54, drawn to a method of identifying potential substrates of an enzyme, classified in class 702, subclass 19. (Requires a species election)
- IV. Claims 55-74, drawn to an array for identifying signal transduction pathways, classified in class 435, subclass 6.
- V. Claims 81-83, 80, and 89-91, drawn to a business method for packing arrays of capture agents classified in class 705, subclass 1.
- VI. Claims 92, drawn to a business method of licensing to a third party the right to manufacture PETs, classified in class 705, subclass 1.
- VII. Claims 93-100, drawn to a method of immunizing a host animal against a disease condition, classified in class 424, subclass 278.1.
- VIII. Claims 101-102, drawn to a computational method of generating antibodies for immunochemistry, classified in class 702, subclass 19.
- IX. Claims 103-107, drawn to a method of detecting a family of related proteins, classified in class 702, subclass 22.
- X. Claims 108-116, drawn to a method of processing a sample for use in PET-associated detection/quantitation of a target protein, classified in class 436, subclass 174.
- XI. Claim 117, drawn to a PET amino acid sequence, classified in class 530, subclass 350.

- XII. Claims 118-125, drawn to method of generating antibodies in an animal, classified in class 435, subclass 41.

The inventions are distinct, each from the other because of the following reasons:

Groups I, III, V – X, and XII are distinct. Inventions are distinct if it can be shown that they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions each have different modes of operations and different functions. For example, Group I is drawn to a method detecting the presence of post-translational modification. Group III is drawn to a method of identifying potential substrates of a enzyme. Group V is drawn to a business method of packing arrays of capture agents. Group VI is drawn to a business method of licensing to a third party the right to manufacture PETs. Group VII is drawn to immunizing a host animal. Group VIII is drawn to a method generating antibodies for immunochemistry. Group IX is drawn to a method of detecting a family of related proteins. Group X is drawn to a method of processing a sample for use in PET-associated detection/quantitation of a target protein. Group XII is drawn to a method generating antibodies in an animal. Each of these groups are drawn to a method that has a different function and different effects. In addition each of these groups have different method steps and have different modes of operation.

Groups II, IV and XI are distinct. Inventions are distinct if it can be shown that they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Group II is drawn to an array of capture

Art Unit: 1631

agents for identifying all potential substrates of a kinase whereas Group IV is drawn to an array for identifying signal transduction pathways. Group I and IV have different effects and would require a different set of capture agents to achieve the different stated goals. Since the Groups have different goals as well as different sets of chemical agents to achieve their goals, the two Groups are distinct. Furthermore, neither of the groups require the amino acid sequence of Group XI. Thus Group XI is a distinct product from Groups II and IV.

Groups I, III, V – X, and XII are related to Groups II and IV as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case Groups I, III, V-X, and XII do not include a step for utilizing an array. Each of the methods disclose may be conducted by studying each capture agent individually and each PET individually. Given that the process as claimed can be practiced by another materially different apparatus or by hand, the inventions are distinct.

Groups I, III, V – X, and XII are related to Group XI as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case each of the Groups I, III, V – X and XII may used to make other PET amino acid sequences.

### ***Linking Claims***

Claims 66, 67 and 68-74 links Groups II and IV. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 66, 67, 68-74. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

### ***Right of Rejoinder***

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or**

**otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.



***Species Requirement***

Group III contains claims directed to the following patentably distinct species of the claimed invention:

Specie A, claim 54, drawn to a method of identifying potential substrates of an enzyme that catalyze a post-translational modification.

Specie B, claims 44-52, drawn to a method of identifying potential substrates of a kinase.

Specie A is distinct from Specie B. Inventions are distinct if it can be shown that they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Since each specie is directed toward a specific class of enzymes, each specie has a different function from the other. Furthermore the results from each specie would also be different. Thus the species have different effects as well as different functions.

If Group III is elected, applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 6:30-5:00, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent

Art Unit: 1631

Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199.

JL

*Ardin H. Marschel 10/16/05*  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**